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788-132—65

In the Supreme Court of the United States

OCTOBER TERM, 1965

No. 495

AN UNDETERMINED NUMBER OF SHIPPING PACKAGES, ETC. VITASAFE CORPORATION

v.

UNITED STATES OF AMERICA

VITASAFE CORPORATION, A CORPORATION, NUTRITIONAL QUALITY CONTROLS, INC., A CORPORATION, THE DOLLAR VITAMINE PLAN, INC., A CORPORATION, LIFE NUTRITION, INC., A CORPORATION, INTERNATIONAL OIL AND METALS CORPORATION, A CORPORATION, DR. PARKER MEDICINE COMPANY, A CORPORATION, PHILIP S. VOLOSOV, AN INDIVIDUAL, AND HENRY D. COHEN, AN INDIVIDUAL, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 50) is reported at 345 F. 2d 864. The opinions of the district court (Pet. App. 13, 41) are reported at 226 F. Supp. 266 and 235 F. Supp. 84.

JURISDICTION

The judgment of the court of appeals was entered on May 27, 1965 (Pet. App. 67). The petition for a writ of certiorari was filed on August 25, 1965. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (21 U.S.C. 301, *et seq.*), provides in pertinent part:

Section 301(a) and (b) [21 U.S.C. 331(a) and (b)]:

> The following acts and the causing thereof are hereby prohibited:
>
> (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
>
> (b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

Section 302(a) [21 U.S.C. 332(a)]:

> The district courts of the United States * * * shall have jurisdiction, for cause shown, * * * to restrain violations of section 301 * * *.

Section 403(a) [21 U.S.C. 343(a)]:

> A food shall be deemed to be misbranded—
>
> (a) If its labeling is false or misleading in any particular.

Section 502(a) and (f)(1) [21 U.S.C. 352(a) and (f)(1)]:

> A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(f) Unless its labeling bears (1) adequate directions for use * * *.

Section 201(g)(3) [21 U.S.C. 321(g)(3)]:

The term "drug" means * * * (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals.

QUESTIONS PRESENTED

1. Whether the product at issue was properly found to have been misbranded in the respects indicated by the district court.

2. Whether the district court was authorized to enjoin petitioners from selling their product on the basis of orders placed on forms contained in their false and misleading promotional material.

STATEMENT

In an *in rem* proceeding under the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, the district court condemned and forfeited about 900 seized packages of Vitasafe vitamin-mineral capsules on the ground that they were misbranded foods and drugs which had been introduced into interstate commerce. Subsequently, the court issued an injunction against petitioners, the Vitasafe Corporation and its subsidiaries, imposing restrictions on the distribution and labeling of Vitasafe capsules.[1]

[1] The district court also condemned and forfeited certain pieces of Vitasafe's promotional material stored in a warehouse, but the court of appeals reversed this portion of the judgment (Pet. App. 54–57).

Vitasafe sells its brand-name capsules, manufactured by various other firms, almost entirely through mail orders, which it solicits through advertisements in newspapers and periodicals and by direct mail. By returning an order blank, which is contained in each advertisement and direct-mail packet, the customer enrolls in a "Plan" under which Vitasafe sends him a 30-day supply of capsules each month until he cancels his enrollment. Ruling that Vitasafe's promotional material constituted "labeling" within the meaning of the Act, the district court found that this labeling, taken as a whole, caused the capsules sold thereunder to be "misbranded" in the following respects:

1. The labeling falsely represents that due to the loss of nutritive value in ordinary foods resulting from soil depletion, storage, processing and cooking, "practically everyone in this country is suffering from or is in danger of suffering from" dietary deficiencies likely to result in certain diseases or conditions (Pet. App. 63).[2]

2. It falsely suggests that the nutritional value of the capsules is enhanced by certain ingredients (Pet. App. 32–34).

3. The labeling represents the capsules to be of value because they contain "lipotropic factors." Since these are "drugs", as that term is defined in Section 201(g)(3) of the Act (21 U.S.C. 321(g)(3)),

[2] Although the district court enjoined the use of such representations without entering an express finding that they were false or misleading, the court of appeals held that "[i]t is apparent that the failure to make such a fact-finding was inadvertent since its basis is amply established by the record" (Pet. App. 63).

the capsules are misbranded because they do not contain adequate directions for use (Pet. App. 36).

4. It falsely represents that specified "Minimum Adult Daily Requirements" are recommended by the National Academy of Science (Pet. App. 34).

5. Although literally correct, the labeling falsely suggests to the ordinary reader that it is necessary to eat enormous amounts and varieties of food to obtain the quantity and variety of vitamins and minerals provided by one capsule (Pet. App. 35).

6. The labeling falsely represents that women, as a class, have nutritional needs different from men and that Vitasafe "Formula M" is created to satisfy the special needs of men, while "Formula W" is designed to fill the special needs of women (Pet. App. 31–32).

7. The labeling falsely represents that the capsules are effective in the treatment of various physical conditions (Pet. App. 35–36).

Accordingly, the court ordered the seized capsules condemned and enjoined petitioners from using labeling which, taken as a whole, contains any of the false and misleading representations mentioned above.

The court of appeals ruled that "[t]he record amply supports both the fact-findings and the order of condemnation with respect to" the seized packages of capsules (Pet. App. 54). It held, however, that the district court's injunction should be modified in certain respects. So far as relevant here, the district court's order, as modified by the court of appeals (Pet. App. 62), enjoins Vitasafe from selling its capsules in interstate commerce:

> to any person who has sent, or will send, to the defendants any of the order forms or order blanks which have been mailed by defendants

> prior to the date of this decree or which have appeared in any newspaper, magazine, Sunday supplement, or other advertisement published prior to the date of this decree * * *. [Emphasis omitted.]

ARGUMENT

1. For the most part, petitioners' contentions amount to a claim that the district court erred in finding that the capsules were misbranded. This evidentiary question does not warrant review by this Court. In any event, we submit, the court's decision is correct. As the court of appeals found, the district court "specified the respects in which the 'labeling' of the condemned capsules misbranded them and the record amply supports the specifications" (Pet. App. 60).

To the extent that the petition attacks the condemnation of the seized Vitasafe capsules, it should be pointed out that the court found those capsules misbranded in seven different respects (*supra*, pp. 4–5). Petitioner directly attacks only the first three of these points (Pet. 5–9, 10–11) and indirectly attacks only the next two (Pet. 9). Therefore, since the statute makes it clear that a food or drug is misbranded "[i]f its labeling is false or misleading *in any particular*" (21 U.S.C. 343(a), 352(a), emphasis added), even if all of petitioners' contentions concerning the court's ruling on misbranding were sound—which we shall show is not the case—that ruling would still be valid.[3] There remains, therefore, only the question whether

[3] The two unchallenged particulars in which Vitasafe's labeling was false or misleading, we note, can in no way be viewed as *de minimis*. See the points numbered 6 and 7, *supra*, p. 5.

the court could properly enjoin petitioners from using labeling which contained any of the first five representations listed in the Statement (*supra*, pp. 4–5).

a. Petitioners argue (Pet. 5–7) that the decision below is in conflict with *United States* v. *119 Cases * * * New Dextra Brand Fortified Cane Sugar*, 334 F. 2d 238 (C.A. 5), in that it rests on the concept of the "average Americen diet" which, they contend, the Fifth Circuit rejected as a basis for finding products misbranded. This argument misconceives both *Dextra* and the case at bar. Pointing out that "[t]his case on appeal presents a very narrow issue" (334 F. 2d 238), the Fifth Circuit in *Dextra* held only that the trial court was not clearly in error in finding that the product's labeling[4] was not false or misleading. The issue here is also narrow, but quite different. The government's evidence showed, and the trial court found, that petitioners' labeling represented that practically everyone in the United States, relying on ordinary foods, suffered from, or was in danger of suffering from, a vitamin deficiency that would probably result in some disease or disorder, and that this representation was false and misleading (see Pet. App. 16–17, 28–29, 63; see also n. 2, *supra*). As the court of appeals expressly ruled, the basis for this finding "is amply established by the record" (Pet. App. 63).

[4] The only allegedly false or misleading representation before the court of appeals in *Dextra* was the statement that "Almost any diet can be nutritionally improved by the use of DEXTRA * * * in place of sweetening agents containing only 'empty' calories—calories unaccompanied by nutrients" (334 F. 2d at 239).

b. Petitioners allege that the court "ruled that the mere listing of the ingredients, for which no need has been established, constitutes misbranding" (Pet. 8), and they attack this ruling as erroneous (Pet. 7–9). Here too, we submit, petitioners misconceive the court's decision. Petitioners were enjoined from using "labeling which when viewed as a whole" falsely suggests that certain ingredients enhance the nutritional value of their product (Pet. App. 45). This order is fully supported by the trial court's findings (Pet. App. 32–34) which, in turn, are fully supported by the record. That the listing of ingredients is required by the Act (21 U.S.C. 343(i)) is immaterial here. Petitioners' product was not found to be misbranded merely because its labeling contained a list of ingredients, as petitioners suggest. Particular portions of a product's labeling, which, standing alone, may be truthful or in accordance with a law or regulation, cannot be relied upon out of context to exculpate the product from condemnation under the Act. The decisions below are in keeping with this Court's comment in *United States* v. *Urbuteit,* 335 U.S. 355, 358, that the problem of enforcing the Federal Food, Drug and Cosmetic Act "is a practical one of consumer protection, not dialectics."

c. Petitioners also attack the district court's finding that their product was misbranded under 21 U.S.C. 352(f)(1) because its labeling did not contain adequate directions for use (Pet. 10–11). The court's decision was based on its finding that "[t]he labeling of the seized article represents it to be of value because it contains 'lipotropic factors'" (Pet.

App. 36). To paraphrase the First Circuit in a similar case, petitioners did not hold out for sale such an esoteric commodity as "lipotropic factors" without having some special purpose in mind. *Nature Food Centres, Inc.* v. *United States,* 310 F. 2d 67, 70, certiorari denied, 371 U.S. 968. In this case, as the trial court found (Pet. App. 36), the only known use of these "factors" is as a "drug" within the meaning of the Act. Therefore, the court concluded, in effect, that petitioners were holding out their product as being, in part, valuable as a "drug." Under the Act, a "drug" is misbranded "[i]f its labeling is false or misleading in any particular" or if its labeling does not bear "adequate directions for use" (21 U.S.C. 352(a), (f)(1)). Petitioners do not, and indeed cannot, demonstrate any basis for upsetting the court's determination that, on the facts of this case, the product was a "drug" and was misbranded in the particulars mentioned above.

d. Petitioners contend that this case raises the issue whether the Act "pertains solely to statements involving the nature, composition, proper use or value of a product" (Pet. 9), although they fail to state their position on this issue. The plain language of the Act answers petitioners' question; misbranding exists if the labeling is false or misleading "in any particular" (21 U.S.C. 343(a), 352(a)). This Court's comments on the precursor of the statute involved here are applicable to the present Act: "The statute is plain and direct. Its comprehensive terms condemn every statement, design and device which may mislead or deceive." *United States* v. *95 Barrels of Vinegar,* 265 U.S. 438, 442–443.

2. Finally, petitioners argue (Pet. 4–5) that the injunction against filling or continuing to fill orders placed on blanks which accompanied its false or misleading promotional material is "punitive" and that "[i]t does not enjoin a future violation of the Act" (Pet. 5). This contention is without substance. As we have noted (*supra*, pp. 3–4), petitioners merchandised their capsules through a "Plan," enrollment in which obligated the customer to make monthly purchases of petitioners' product until he cancelled his membership. Under this arrangement, petitioners' misbranding produced continuing effects, which the court's order was properly tailored to remedy. As the district court found, "Present consumers of Vitasafe products became customers as subjects of the condemned ads. Any vitamins sold by Vitasafe to such customers now is as much mislabeled by that advertising as if it had been sold to them before the condemnation decree" (Pet. App. 48).

CONCLUSION

For the reasons stated, it is respectfully submitted that the petition for a writ of certiorari should be denied.

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